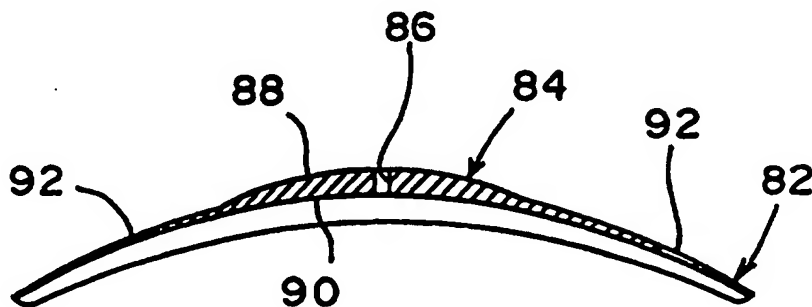


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | |
|--|-----------|---|
| (51) International Patent Classification ⁶ : A61F 2/13 | A1 | (11) International Publication Number: WO 96/10968 (43) International Publication Date: 18 April 1996 (18.04.96) |
| (21) International Application Number: PCT/US95/12614 (22) International Filing Date: 5 October 1995 (05.10.95) (30) Priority Data: 08/318,991 6 October 1994 (06.10.94) US (71)(72) Applicant and Inventor: FEINGOLD, Vladimir [US/US]; 31732 Isle Vista, Laguna Nigel, CA 92677 (US). (74) Agent: KLIMA, William, L.; Klima & Hopkins, P.C., Suite 905, Crystal Plaza One, 2001 Jefferson Davis Highway, Arlington, VA 22202-3603 (US). | | (81) Designated States: AL, AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TM, TT, UA, UG, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG). Published <i>With international search report.</i> |

(54) Title: INTRAOCULAR CONTACT LENS AND METHOD OF IMPLANTATION**(57) Abstract**

This invention is an intraocular contact lens (10, 20, 30, 40, 50, 60, 70, 80) for implantation into the eye. The intraocular contact lens is provided with a transition between a lens portion and lens body portion to minimize edge formation that could potentially damage or wear the back of the iris. Further, the intraocular contact lens can have a variety of features including a groove (G) on the anterior surface for enhancing lubrication between the intraocular contact lens and the back of the iris, an air passageway (86) for equalizing the pressure between the anterior and posterior surface, and one or more indents (92) for manipulating the intraocular contact lens under the eye during the implantation operation while preventing contact of the natural lens with the tip of the manipulating instrument.



BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | |
|----|--------------------------|----|---------------------------------------|----|--------------------------|
| AT | Austria | GB | United Kingdom | MR | Mauritania |
| AU | Australia | GE | Georgia | MW | Malawi |
| BB | Barbados | GN | Guinea | NE | Niger |
| BE | Belgium | GR | Greece | NL | Netherlands |
| BF | Burkina Faso | HU | Hungary | NO | Norway |
| BG | Bulgaria | IE | Ireland | NZ | New Zealand |
| BJ | Benin | IT | Italy | PL | Poland |
| BR | Brazil | JP | Japan | PT | Portugal |
| BY | Belarus | KE | Kenya | RO | Romania |
| CA | Canada | KG | Kyrgyzstan | RU | Russian Federation |
| CF | Central African Republic | KP | Democratic People's Republic of Korea | SD | Sudan |
| CG | Congo | KR | Republic of Korea | SE | Sweden |
| CH | Switzerland | KZ | Kazakhstan | SI | Slovenia |
| CI | Côte d'Ivoire | LI | Liechtenstein | SK | Slovakia |
| CM | Cameroon | LK | Sri Lanka | SN | Senegal |
| CN | China | LU | Luxembourg | TD | Chad |
| CS | Czechoslovakia | LV | Latvia | TG | Togo |
| CZ | Czech Republic | MC | Monaco | TJ | Tajikistan |
| DE | Germany | MD | Republic of Moldova | TT | Trinidad and Tobago |
| DK | Denmark | MG | Madagascar | UA | Ukraine |
| ES | Spain | ML | Mali | US | United States of America |
| FI | Finland | MN | Mongolia | UZ | Uzbekistan |
| FR | France | | | VN | Viet Nam |
| GA | Gabon | | | | |

5 **INTRAOCULAR CONTACT LENS AND METHOD OF IMPLANTATION**

10 **FIELD OF THE INVENTION**

 This invention relates to intraocular contact lens and methods of implanting
intraocular contact lens in the eye. Specifically this invention relates to contact lens
15 for surgical implantation in the human eye, and to methods of implanting an intraocular
contact lens in the human eye.

20 **BACKGROUND OF THE INVENTION**

 Traditionally, contact lens were developed and marketed for use on the exterior
surface of the eye. The contact lens were initially all made from glass material,
however, glass has been substantially replaced with synthetic plastic materials,
particularly materials that minimize any reaction by the eye.

25 In 1989, the Russians disclosed a silicon intraocular contact lens. Figure 26
shows an eye fitted with the Russian intraocular contact lens revealing its method of
attachment in the eye. Specifically, the intraocular contact lens 200 includes a curved
lens body 202 in contact with the natural crystalline eye lens 204. In the center of the
curved lens body 202 extends a protrusion 206 defining an annular groove 208 with the
30 curved lens body 202. The protrusion 206 is fitted through the iris 210 so that the
inner circular edge 212 of the iris 210 is received within the annular groove 208.

 In 1991, the Russians again disclosed a new silicon intraocular lens 300. Figure
27 shows a transverse cross-sectional view of the intraocular lens having a curved body
portion 302 with an annular protrusion 304. The annular protrusion 304 defines a
35 substantially sharp circular edge 306. This particular lens has experienced some
difficulties in use due to the substantially sharp circular edge 306 scraping against the

- 5 inside surface of the iris repeatedly when the iris changes size causing pigment from the iris to be scraped from the iris.

SUMMARY OF THE INVENTION

- 10 An object of the present invention is to provide an improved intraocular contact lens.

Another object of the present invention is to provide an intraocular contact lens having an outer surface curvature that minimizes wear or damage to the back surface of the iris.

- 15 Another further object of the present invention is to provide an intraocular contact lens with a smooth transition between the lens body portion and lens portion on the outer surface of the intraocular contact lens.

- 20 An even further object of the present invention is to provide an intraocular contact lens having at least one circular groove, in particular a circular groove, in the outer surface thereof.

Another further object of the present invention is to provide an intraocular contact lens a through hole or passage between the posterior and anterior surface of the intraocular contact lens in order to equalize the intraocular pressure.

- 25 An object of the present invention is to provide an improved method of implantation of an intraocular contact lens.

These and other objects of the present invention can be provided by various concepts that improve the configuration and arrangement over prior art intraocular contact lenses.

- 30 The intraocular contact lens according to the present invention is provided with an outer radius of curvature between the lens body portion and the lens portion that smoothly transitions therebetween. Specifically, there exists a transition in the outer radius of curvature of the lens between the lens body portion and the center lens portion. It is important that the transition in the radius of curvature between these two portions or zones is such that there is minimum edge formation so as to prevent damage

5 or wear to the back of the iris. A transition can be made that has a gradient of radius of curvature within very small dimensions at the transition between the lens body portion and the center lens portion so that the transition is smooth. Such an arrangement works well within the eye and does not appear to damage or wear the back of the iris, and is a significant improvement over the prior art intraocular contact lenses
10 derived from Russia that do cause damage and wear to the back of the iris.

Another concept according to the present invention is to provide at least one groove in the anterior surface of the intraocular contact lens. The groove can be a single groove or a pattern of grooves, and the groove(s) can be circular shaped, straight shaped, curve shaped, or combinations of shapes thereof. Further, the cross-sectional
15 shape of the groove can be one-half circle, square, V-shaped or other suitable cross-sectional shape.

The groove is preferably in the arrangement of a circular groove located in the lens body portion and surrounding the lens body. This circular groove allows for good circulation of eye fluid that facilitates lubrication between the intraocular contact lens and the back of the iris. Other groove configurations can be utilized, however, the
20 circular configuration appears to work very well.

A further concept according to the present invention is to provide a passageway in the intraocular contact lens between the posterior and anterior surface of the intraocular contact lens to equalize the intraocular pressure between the anterior surface and posterior surface of the intraocular contact lens allowing for an equalization of
25 pressure between the anterior chamber and posterior chamber of the eye. The passageway can be provided in a variety of different forms including grooves in the anterior surface and posterior surface that connect together forming a continuous air passageway, a hole or other type of air passageway through the thickness dimension
30 of the intraocular contact lens at one or more specific locations. For example, both the anterior surface and posterior surface of the intraocular contact lens can be provided each with a circular shaped groove and a single radial outwardly extending groove extending from the circular groove to the edge of the intraocular lens with both radial outwardly extending grooves meeting at the same peripheral position providing a

5 continuous air passageway connecting the circular shaped grooves. In another embodiment, preferably one or more holes are provided near the perimeter of the intraocular contact lens. In a further embodiment, more preferably, a hole is provided in the center of the intraocular contact lens along the optical axis of the intraocular contact lens that provides the best location for equalization of intraocular pressure, and
10 does not effect the optics of the intraocular contact lens.

An even further concept is to provide blind holes in the anterior surface of the intraocular contact lens to be used in the process of lens insertion and positioning the intraocular contact lens under the iris without touching the natural lens.

The method of implanting an intraocular contact lens according to the present
15 invention includes placing the intraocular lens in the posterior chamber of the eye between the natural human crystalline lens and the iris. Further, an important procedure in the implantation method includes providing one or more through holes in the iris to place the anterior chamber and posterior chamber in fluid communication to allow equalization of pressure therebetween. This prevents the intraocular contact lens
20 being sucked into tight contact with the back of the iris potentially causing significant damage and wear to the back of the iris. This affect is due to a differential pressure between the posterior and anterior chambers. Thus, the one or more through holes alleviates the situation.

25 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a cross-sectional view of a positive intraocular contact lens according to the present invention, as indicated in Figure 3.

Figure 2 is a cross-sectional view of the intraocular lens in Figure 1, as
30 indicated in Figure 3.

Figure 3 is a top planar view of the positive intraocular lens as shown in Figures 1 and 2.

Figure 4 is a cross-sectional view of another embodiment of a positive intraocular contact lens according to the present invention, as indicated in Figure 6.

5 Figure 5 is a cross-sectional view of the positive intraocular contact lens shown in Figure 4, as indicated in Figure 6.

 Figure 6 is a top planar view of the positive intraocular contact lens as shown in Figures 5 and 6.

10 Figure 7 is a table of examples of positive intraocular contact lenses directed to the two embodiments shown in Figures 1-6.

 Figure 8 is a cross-sectional view of a negative intraocular contact lens according to the present invention, as indicated in Figure 10.

 Figure 9 is a cross-sectional view of the negative intraocular contact lens shown in Figure 8, as indicated in Figure 10.

15 Figure 10 is a top planar view of the negative intraocular contact lens shown in Figures 8 and 9.

 Figure 11 is another embodiment of a negative intraocular contact lens according to the present invention, as indicated in Figure 12.

20 Figure 12 is a cross-sectional view of the intraocular lens shown in Figure 11, as indicated in Figure 13.

 Figure 13 is a top planar view of the negative intraocular contact lens shown in Figures 11 and 12.

 Figure 14 is a table of examples of negative intraocular lenses directed to the two embodiments shown in Figure 8-13.

25 Figure 15 is a top planar view of another embodiment of a positive intraocular contact lens according to the present invention.

 Figure 16 is a cross-sectional view of the positive intraocular contact lens, as indicated Figure 15.

30 Figure 17 is a partial detailed cross-sectional view of a portion of the positive intraocular lens shown in Figures 15 and 16, illustrating the detailed curvature thereof.

 Figure 18 is a table indicating the detailed curvature as an example of the embodiment of the positive intraocular lens shown in Figures 15-17.

 Figure 19 is another embodiment of a negative intraocular contact lens according to the present invention.

5 Figure 20 is a top planar view of another negative intraocular contact lens according to the present invention with a circular groove in the lens body portion thereof.

 Figure 21 is a cross-sectional view of the negative intraocular contact lens, as indicated in Figure 20.

10 Figure 22 is a top planar view of a preferred embodiment of an intraocular contact lens according to the present invention provided with a through hole in the optical center thereof.

 Figure 23 is a cross-sectional view of the intraocular contact lens, as indicated in Figure 20.

15 Figure 24 is a cross-sectional view of an eye having an intraocular contact lens according to the present invention implanted therein.

 Figure 25 is a cross-sectional view the eye with a prior art intraocular contact lens implanted therein.

 Figure 26 is a cross-sectional view of another embodiment of a prior art intraocular contact lens.

20

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

25 An embodiment of a positive intraocular contact lens according to the present invention as shown in Figures 1-3.

 The intraocular contact lens 10 is defined by an oval-shaped lens body portion 12 defined by major axis diameter DM and minor axis diameter Dm , and radius $R2$, and a circular shaped lens portion 14 having a diameter Do .

30 The lens portion 14 has a thickness Tc and the lens body portion 12 has an edge thickness Te , as shown in Figure 1. Further, the lens portion 14 has a curvature $SRfr$, and the lens body portion 12 has an outer curvature SRo and an inner curvature Sri .

 Another embodiment of a positive intraocular contact lens according to the present invention as shown in Figures 4-6.

5 The intraocular contact lens 20 is defined by an oval-shaped lens body portion 22 defined by major axis diameter DM and minor axis diameter Dm, and a radius R2, and a circular shaped lens portion 24 having a diameter Do.

 The lens portion 24 has a thickness Tc and the lens body portion 22 has an edge thickness Te, as shown in Figure 4. Further, the lens portion 24 has a curvature SRfr and the lens body portion 22 has an outer curvature SRfr2 (SRo) and an inner curvature Sri.

 Specific examples of the positive intraocular contact lens are given in the table in Figure 7. In these examples, $T = 0.05 \pm 0.02\text{mm}$, $Sro = 9.4 \pm 0.1$, $Sri = 9.8$, $DM = 10.5 \pm 0.1\text{mm}$, $Dm = 6 \pm 0.3\text{mm}$ and $R2 \pm 0.1$.

15 An embodiment of a negative intraocular contact lens according to the present invention as shown in Figures 8-10.

 The intraocular contact lens 30 is defined by an oval-shaped lens body portion 32 defined by major axis diameter DM and minor axis diameter Dm, and having a radius R2, and a circular shaped lens portion 34 having a diameter Do.

20 The lens portion 34 has a thickness Tc and the lens body portion 32 has an edge thickness Te, as shown in Figure 8. Further, the lens portion 34 has a curvature SRfr and the lens body portion 32 has an outer curvature SRo and an inner curvature Sri.

 Another embodiment of a negative intraocular contact lens according to the present invention as shown in Figures 11-13.

25 The intraocular contact lens 40 is defined by an oval-shaped lens body portion 42 defined by major axis diameter DM and minor axis diameter Dm, and having a radius R2, and a circular shaped lens portion 44 having a diameter Do.

 The lens portion 44 has a thickness Tc and the lens body portion 42 has an edge thickness Te, as shown in Figure 11. Further, the lens portion 44 has a curvature SRfr and the lens body portion 42 has an outer curvature SRfr2 (SRo) and an inner curvature Sri.

30 Specific examples of the positive intraocular contact lens are given in the table in Figure 14. In these examples, $T = 0.05 \pm 0.02\text{mm}$, $Sro = 9.4 \pm 0.1$, $Sri = 9.8$, $DM = 10.5 \pm 0.1\text{mm}$, $Dm = 6 \pm 0.3\text{mm}$ and $R2 \pm 0.1$.

5 A further embodiment of a positive intraocular contact lens 50 is shown in Figures 15-17.

 The intraocular contact lens 50 is defined by an oval-shaped lens body portion 52 defined by major axis diameter DM and minor axis diameter Dm , and radius $R2$, and a circular shaped lens portion 54 having a diameter Do . The lens portion 54 has
10 a thickness Tc and the lens body portion 52 has an edge thickness Te , as shown in Figure 16.

 The detail curvature of the intraocular contact lens is shown in Figure 17. An example of this particular lens is given in the table in Figure 18 with the designations $R1$ - $R8$ corresponding to Figure 17.

15 A further embodiment of a negative intraocular contact lens 60 is shown in Figure 19. The advantage of this embodiment is that a small gap exists between the intraocular contact lens center and the natural lens allowing for flow of body fluids, and to minimize friction which could potentially cause mechanical damage and cataracts in the eye.

20 An even further embodiment of a negative intraocular contact lens 70 is shown in Figure 20.

 The intraocular contact lens 70 is defined by an oval-shaped lens body portion 72 defined by major axis diameter DM and minor axis diameter Dm , and a circular shaped lens portion 74 having a diameter Do . The lens portion 74 has a thickness Tc
25 and the lens body portion 72 has an edge thickness Te , as shown in Figure 21.

 The important feature of this embodiment is the circular groove G provided in the lens body portion 72 surrounding the lens portion 74. The circular groove G allows for circulation of fluid inside the eye. Further, the groove G can be used for lens manipulation during surgery, and facilitates the equalization of intraocular
30 pressure.

 A preferred embodiment of an intraocular contact lens 80 having a lens body portion 82 and lens portion 84, as shown in Figs. 22 and 23. In this embodiment, an air passageway 86 (e.g. hole) is provided in the center optical axis of the lens portion 84 for equalizing the pressure between the anterior surface 88 and posterior surface 90

5 of the intraocular contact lens 80. This air passageway 86 allows for equalization of pressure between the anterior chamber and posterior chamber of the eye. Otherwise, a significant suction or negative pressure can occur on the anterior surface of the intraocular contact lens sucking the back of the iris into contact therewith and causing damage or wear to the iris.

10 The intraocular contact lens 80 is provided with a pair of indents 92, as shown in Figs. 22 to 24, for allowing the intraocular contact lens 80 to be manipulated under the iris during the implantation operation. The indents 92 are significantly better than through holes for purposes of manipulation, since the bottoms of the indents prevent penetration of a manipulating tool through the lens and inadvertently into contact with
15 the natural lens that would cause an immediate cataract of the natural lens.

Figure 25 illustrates the manner in which an intraocular contact lens 100 according to the present invention is located in the eye.

The intraocular contact lens 100 is positioned over the natural crystalline lens 102 and underneath the iris 104. The intraocular contact lens 100 is located in the
20 posterior chamber 106.

As an alternative or in addition to providing an air passageway in the intraocular contact lens between the anterior surface and posterior surface thereof, at least one through hole 108 can be provided in the iris 104 providing a conduit between the posterior chamber 106 and anterior chamber 110. The hole 108 allows for equalization
25 of the pressure between the posterior chamber 106 and the anterior chamber 110 so that the iris 104 is not continuously sucked into contact with the intraocular contact lens potentially causing damage or wear to the back of the iris 104.

5 CLAIM:

1. An intraocular contact lens, comprising:
a center lens portion; and
a lens body portion surrounding said center lens portion, said center lens portion
10 and said lens body portion defining a continuous outer surface having a smooth
transition between an outer surface of said center lens portion and an outer surface of
said lens body portion.
2. A lens according to Claim 1, wherein said smooth transition is defined by a
15 gradient of varying outer surface curvature in a relative small distance between said
outer surfaces.
3. A lens according to Claim 2, wherein a gradient of said smooth transition
between said center lens portion and said lens body portion is within the range of 2 to
20 6 diopter in power.
4. A lens according to Claim 1, including at least one groove provided in an outer
surface of the lens.
- 25 5. A lens according to Claim 4, wherein said groove is a circular shaped groove.
6. A lens according to Claim 5, wherein said circular groove is located in said
outer surface of said lens body portion.

5 7. A lens according to Claim 4, wherein said groove is a straight groove.

8. A lens according Claim 4, wherein said groove is a curved shaped groove.

9. A lens according to Claim 1, including at least one passageway for equalizing
10 the pressure between an anterior surface and posterior surface of the intraocular contact
lens.

10. A lens according to Claim 9, wherein said passageway is a hole through a
thickness dimension of the intraocular contact lens.

15 11. A lens according to Claim 10, wherein said hole is located in a center of said
center lens portion.

12. A lens according to Claim 10, wherein said hole is located in the center of an
20 optical axis of the intraocular contact lens.

13. An intraocular contact lens, comprising:
a center lens portion;
a lens body portion surrounding said center lens portion; and at least one groove
25 in an anterior surface of the lens.

- 5 14. A lens according to Claim 13, wherein said at least one groove is a circular groove to facilitate circulation of eye fluid.
15. A lens according to Claim 13, wherein said circular groove is located in an anterior surface of said lens body portion.
- 10 16. A lens according to Claim 14, wherein said groove has a half circle cross-sectional shape.
- 15 17. A lens according to Claim 13, wherein said center lens portion and said lens body portion define a continuous outer surface having a smooth transition between an outer surface of said center lens portion and an outer surface of said lens body portion.
- 20 18. A lens according to Claim 13, including at least one passageway for equalizing the pressure between an anterior surface and posterior surface of the intraocular contact lens.
- 25 19. A lens according to Claim 14, including at least one passageway for equalizing the pressure between an anterior surface and posterior surface of the intraocular contact lens.
20. An intraocular contact lens, comprising:
a center lens portion;

- 5 a lens body portion surrounding said center lens portion; and
at least one passageway for equalizing the pressure between an anterior surface
and posterior surface of the intraocular contact lens.
21. A lens according to Claim 20, wherein said passageway is located in a center
10 of said center lens portion.
22. A lens according to Claim 20, including at least one groove in an anterior
surface of the intraocular contact lens to facilitate circulation of eye fluid.
- 15 23. A lens according to Claim 20, wherein said center lens portion and said lens
body portion define a continuous outer surface having a smooth transition between an
outer surface of said center lens portion and an outer surface of said lens body portion.
24. A lens according to Claim 21, wherein said center lens portion and said lens
20 body portion define a continuous outer surface having a smooth transition between an
outer surface of said center lens portion and an outer surface of said lens body portion.
25. A method of implantation of an intraocular contact lens, comprising the steps
of:
25 making an incision in the eye;
inserting an intraocular contact lens inside the eye;

- 14 -

5 making at least one through hole in the iris to fluidly connect posterior and
anterior chambers of the eye; and
closing the incision in the eye.

26. A method according to Claim 25, wherein said contact lens has a smooth
10 transition between and outer surface of a center lens portion and outer surface of a lens
body portion of the lens.

27. A method according to Claim 25, wherein said contact lens includes a least one
groove on the outer surface of the lens.

15

1/12

FIG. 1

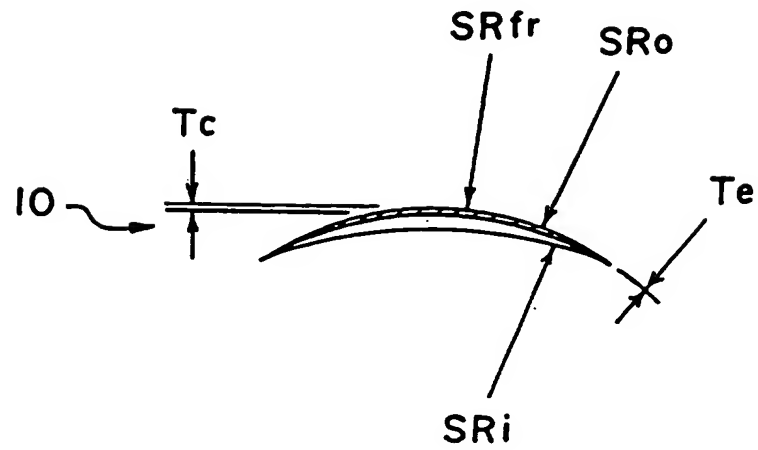


FIG. 2

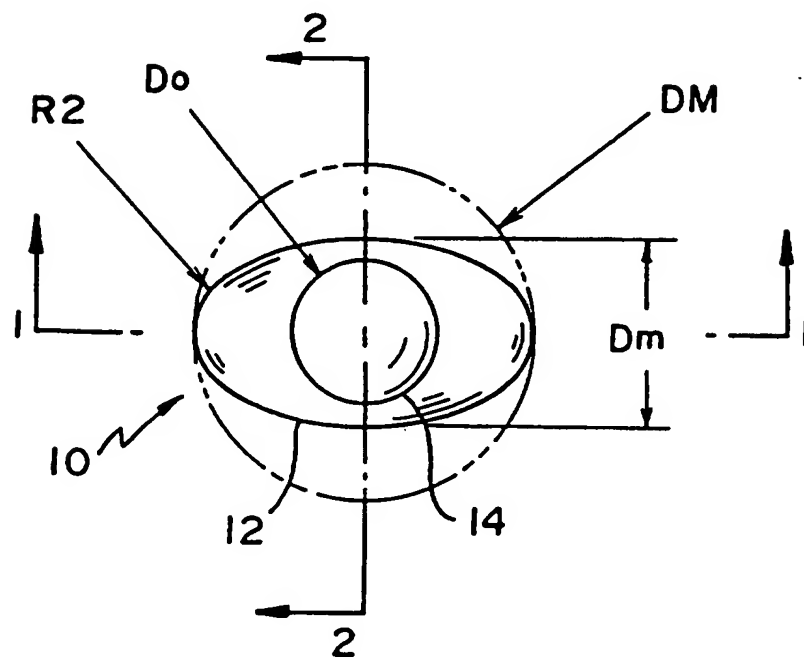


FIG. 3

2/12

FIG. 4

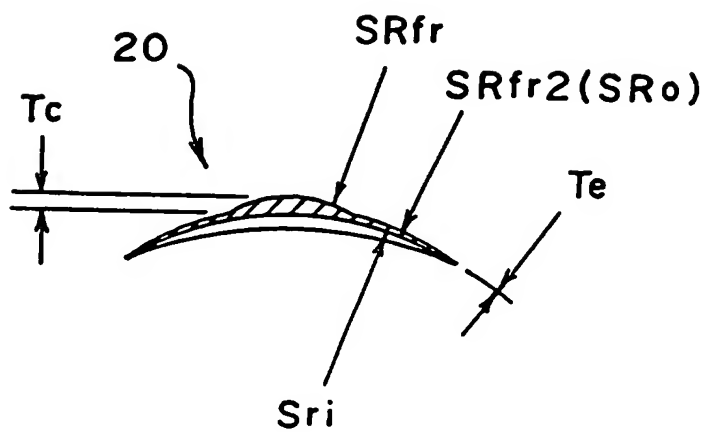


FIG. 5

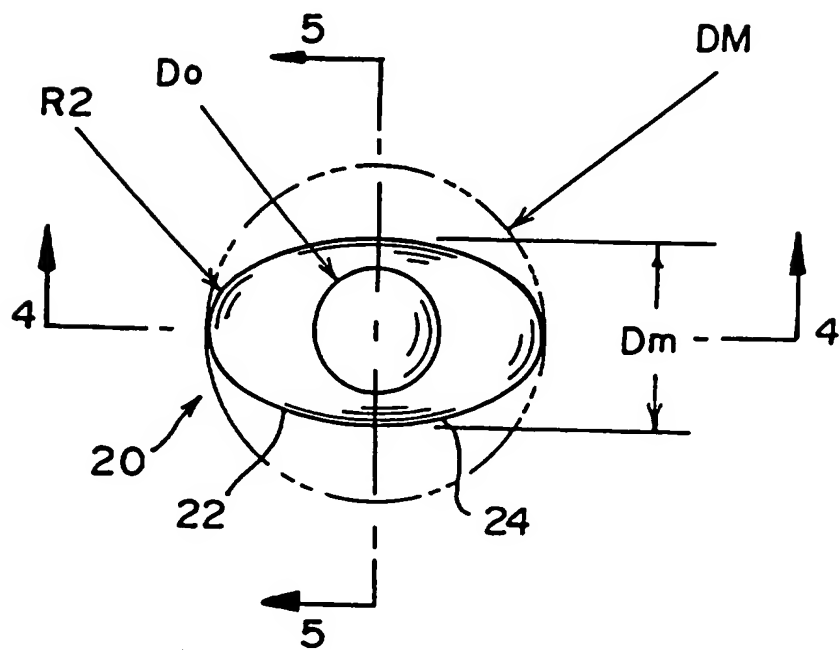


FIG. 6

3 / 12

| IC2020 (POSITIVE) | | | |
|--------------------|----------------|---------------|---------|
| DIOPTER NOMINAL | $T_c \pm 0.05$ | $D_o \pm 0.1$ | Rfr |
| | | | NOMINAL |
| A 3.0 | 0.18 | 4.50 | 7.91 |
| 3.5 | 0.20 | 4.50 | 7.65 |
| 4.0 | 0.22 | 4.50 | 7.40 |
| 4.5 | 0.23 | 4.50 | 7.16 |
| 5.0 | 0.24 | 4.50 | 6.95 |
| 5.5 | 0.25 | 4.50 | 6.74 |
| 6.0 | 0.27 | 4.50 | 6.55 |
| 6.5 | 0.28 | 4.50 | 6.36 |
| 7.0 | 0.29 | 4.50 | 6.19 |
| 7.5 | 0.30 | 4.50 | 6.02 |
| 8.0 | 0.32 | 4.50 | 5.87 |
| 8.5 | 0.33 | 4.50 | 5.72 |
| 9.0 | 0.34 | 4.50 | 5.58 |
| 9.5 | 0.35 | 4.50 | 5.45 |
| 10.0 | 0.36 | 4.50 | 5.32 |
| 10.5 | 0.38 | 4.50 | 5.20 |
| 11.0 | 0.39 | 4.50 | 5.08 |
| 11.5 | 0.40 | 4.50 | 4.97 |
| 12.0 | 0.40 | 4.37 | 4.86 |
| 12.5 | 0.40 | 4.29 | 4.76 |
| 13.0 | 0.40 | 4.20 | 4.66 |
| 13.5 | 0.40 | 4.13 | 4.57 |
| 14.0 | 0.40 | 4.05 | 4.48 |
| 14.5 | 0.40 | 4.00 | 4.39 |
| 15.0 | 0.45 | 4.00 | 4.31 |
| 15.5 | 0.45 | 4.00 | 4.23 |
| 16.0 | 0.45 | 4.00 | 4.15 |
| 16.5 | 0.45 | 4.00 | 4.08 |
| B 17.0 | 0.45 | 3.96 | 4.01 |

FIG. 7

FIG. 8

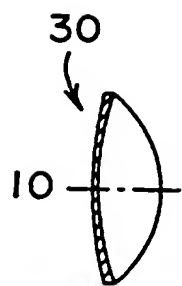
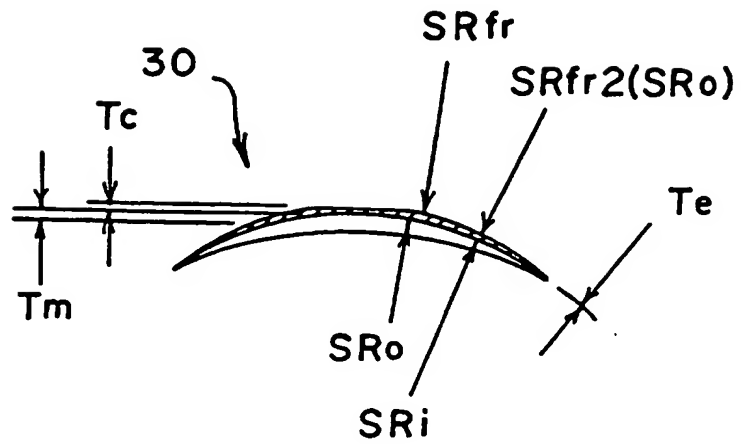


FIG. 9

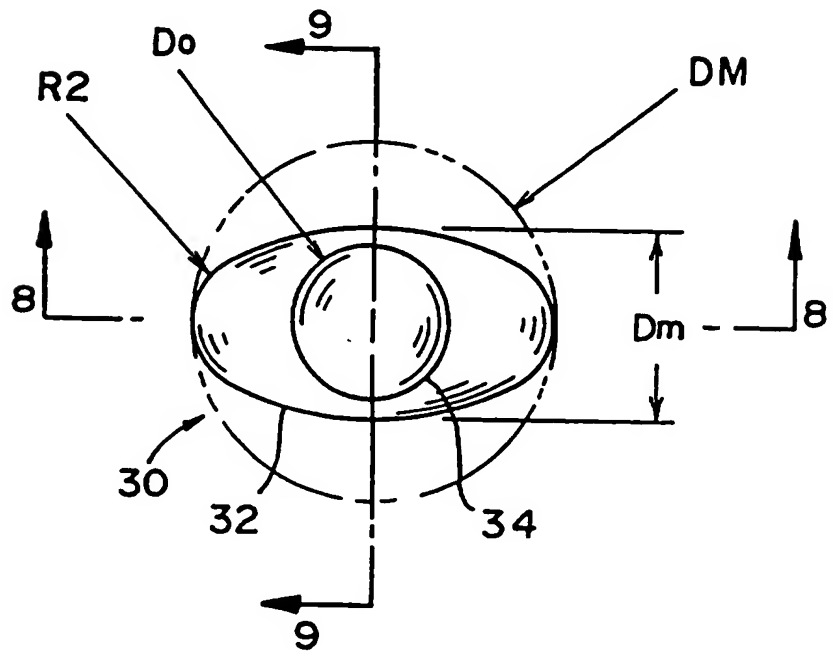


FIG. 10

5/12

FIG. 11

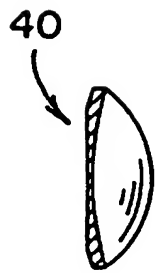
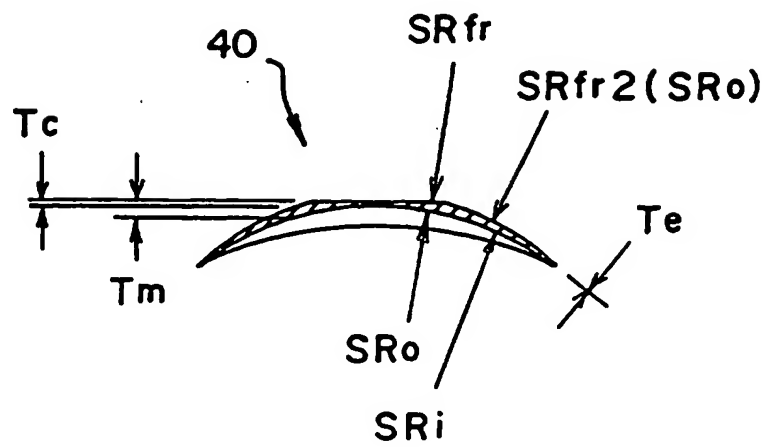


FIG. 12

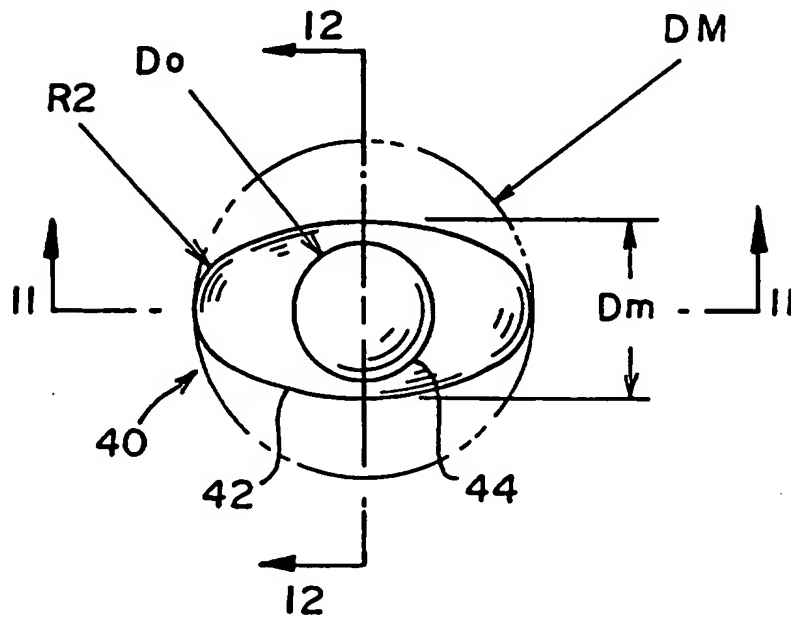


FIG. 13

6/12

| IC2020 (NEGATIVE) | | | | | | | |
|--------------------|---------|---------|--------|---------|--------|------|-------|
| DIOPTER NOMINAL | Tc±0.05 | Tm±0.05 | Do±0.1 | Rfr | Rfr2 | Ro | |
| | | | | NOMINAL | | | |
| A | -3.0 | 0.21 | 0.30 | 5.0 | 13.64 | 8.93 | 10.00 |
| | -3.5 | 0.20 | 0.30 | 5.0 | 14.51 | 8.93 | 10.00 |
| | -4.0 | 0.19 | 0.30 | 5.0 | 15.50 | 8.93 | 10.00 |
| | -4.5 | 0.17 | 0.30 | 5.0 | 16.64 | 8.93 | 10.00 |
| | -5.0 | 0.16 | 0.30 | 5.0 | 17.96 | 8.93 | 10.00 |
| | -5.5 | 0.14 | 0.30 | 5.0 | 19.51 | 8.93 | 10.00 |
| | -6.0 | 0.13 | 0.30 | 5.0 | 21.34 | 8.93 | 10.00 |
| | -6.5 | 0.12 | 0.30 | 5.0 | 23.56 | 8.93 | 10.00 |
| | -7.0 | 0.10 | 0.30 | 5.0 | 26.30 | 8.93 | 10.00 |
| | -7.5 | 0.09 | 0.30 | 5.0 | 29.76 | 8.93 | 10.00 |
| | -8.0 | 0.07 | 0.30 | 5.0 | 34.26 | 8.93 | 10.00 |
| | -8.5 | 0.06 | 0.30 | 5.0 | 40.38 | 8.93 | 10.00 |
| | -9.0 | 0.12 | 0.35 | 4.8 | 49.18 | 8.76 | 10.00 |
| | -9.5 | 0.10 | 0.35 | 4.8 | 62.83 | 8.76 | 10.00 |
| | -10.0 | 0.09 | 0.35 | 4.8 | 86.99 | 8.76 | 10.00 |
| | -10.5 | 0.08 | 0.35 | 4.8 | 141.34 | 8.76 | 10.00 |
| | -11.0 | 0.07 | 0.35 | 4.8 | 376.86 | 8.76 | 10.00 |
| B | -11.5 | 0.09 | 0.35 | 4.5 | 100000 | 8.78 | 9.83 |
| | -12.0 | 0.08 | 0.35 | 4.5 | 100000 | 8.78 | 9.42 |
| | -12.5 | 0.07 | 0.35 | 4.5 | 100000 | 8.78 | 9.04 |
| | -13.0 | 0.10 | 0.40 | 4.5 | 100000 | 8.61 | 8.69 |
| | -13.5 | 0.09 | 0.40 | 4.5 | 100000 | 8.61 | 8.37 |
| | -14.0 | 0.08 | 0.40 | 4.5 | 100000 | 8.61 | 8.07 |
| | -14.5 | 0.07 | 0.40 | 4.5 | 100000 | 8.61 | 7.79 |
| | -15.0 | 0.11 | 0.45 | 4.5 | 100000 | 8.46 | 7.53 |
| | -15.5 | 0.09 | 0.45 | 4.5 | 100000 | 8.46 | 7.29 |
| | -16.0 | 0.08 | 0.45 | 4.5 | 100000 | 8.46 | 7.06 |
| | -16.5 | 0.07 | 0.45 | 4.5 | 100000 | 8.46 | 6.85 |
| -17.0 | 0.06 | 0.45 | 4.5 | 100000 | 8.46 | 6.65 | |

FIG. 14

7/12

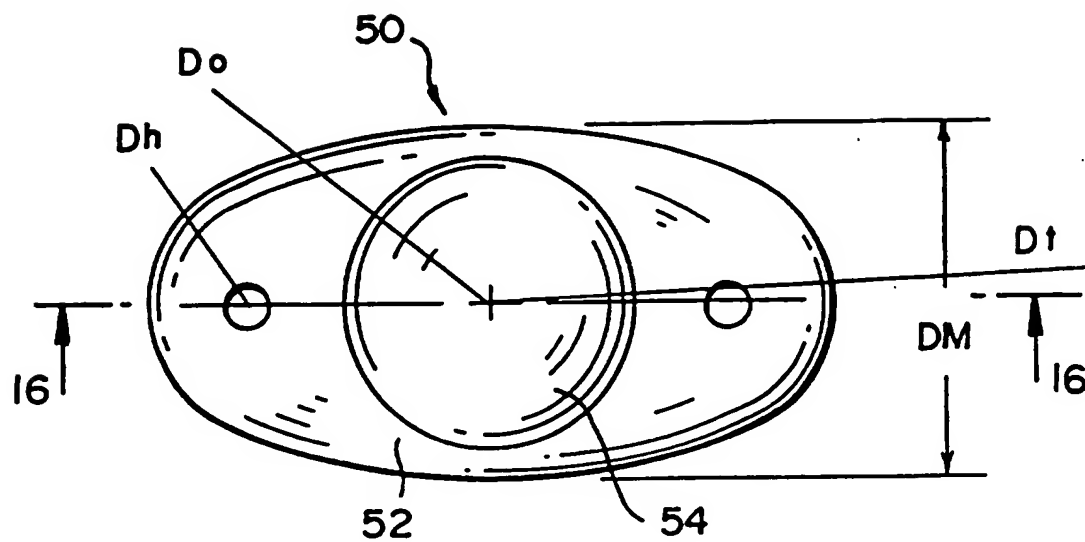


FIG. 15

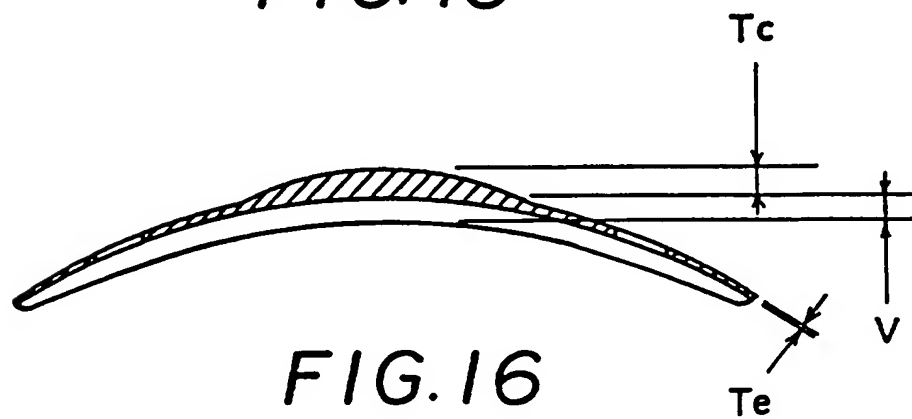


FIG. 16

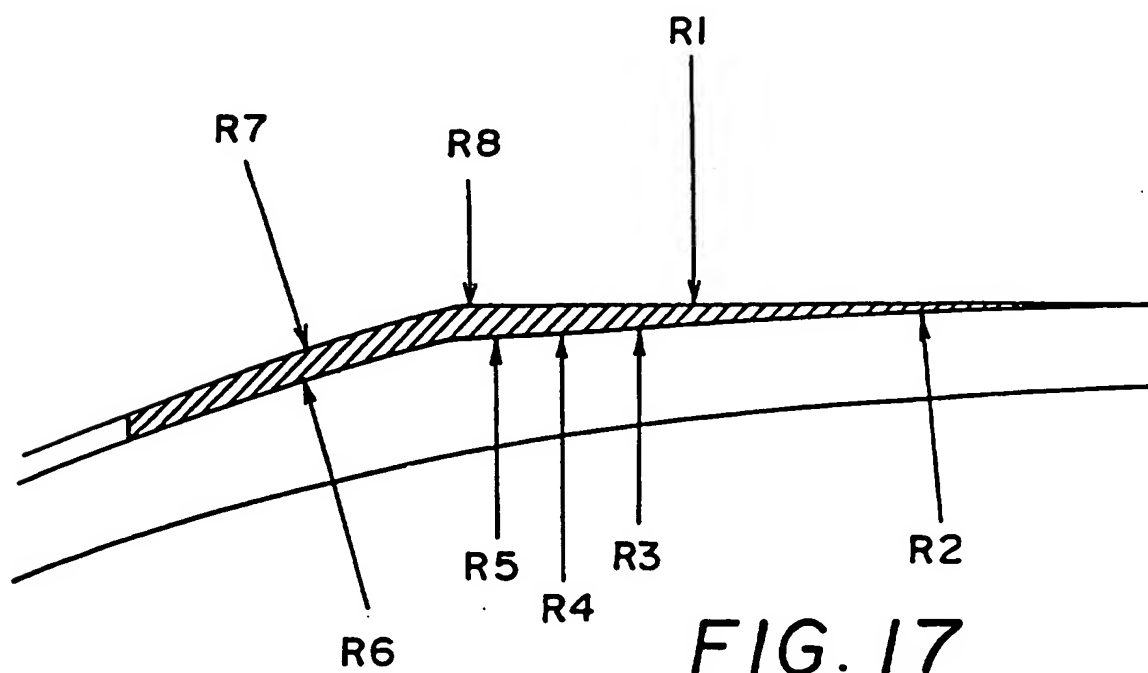
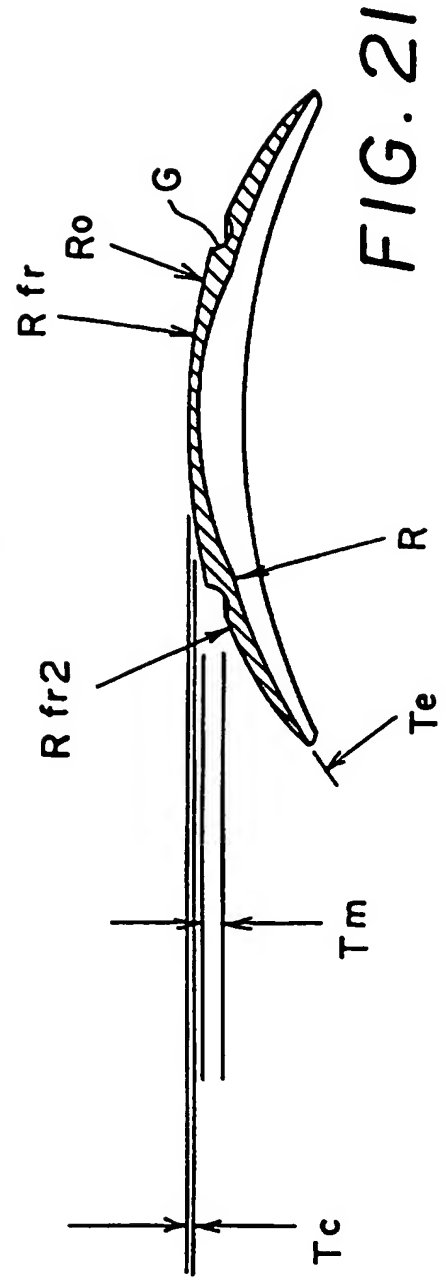
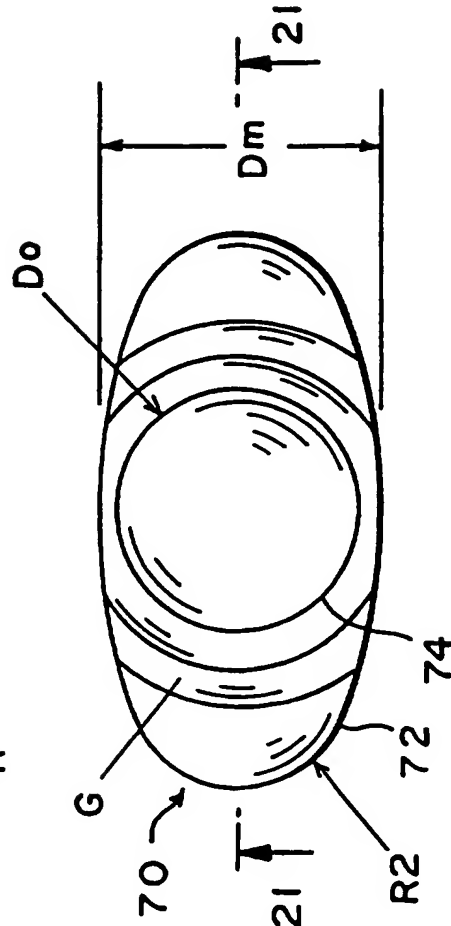
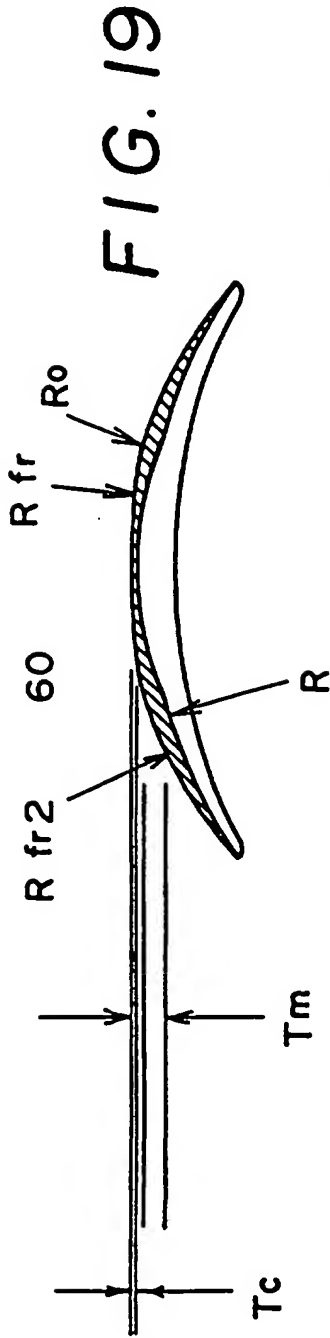


FIG. 17

8/12

| | | | |
|--|----------------------------------|--------|-----------|
| | | | |
| | | | |
| | Example - (100ph2, - 10 Diopter) | | |
| | | | |
| | | R1[mm] | 100000.00 |
| | | R2[mm] | 11.96 |
| | | R3[mm] | 13.80 |
| | | R4[mm] | 15.75 |
| | | R5[mm] | 18.70 |
| | | R6[mm] | 10.00 |
| | | R7[mm] | 8.96 |

FIG. 18



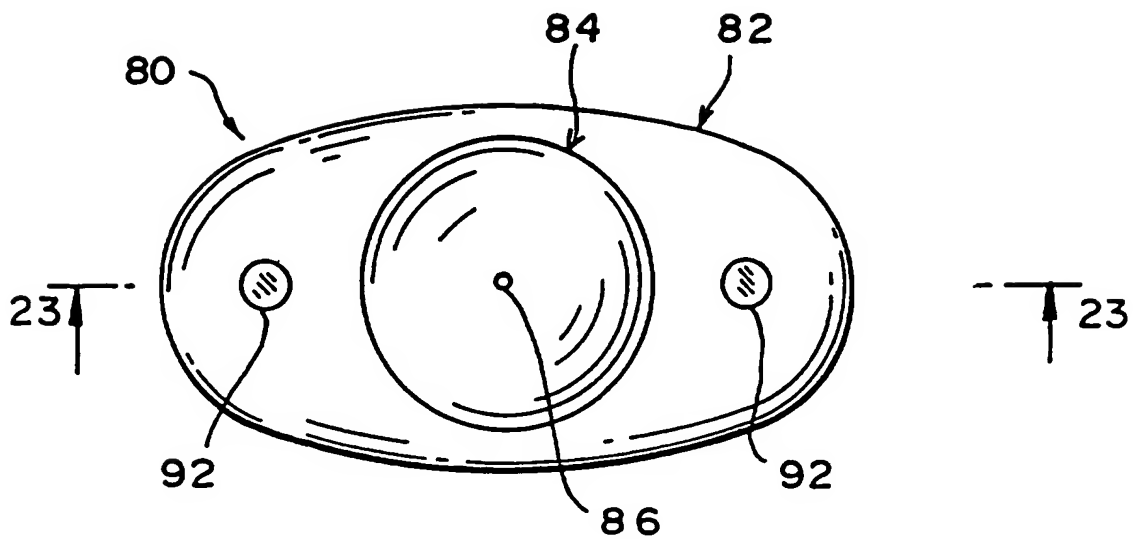


FIG. 22

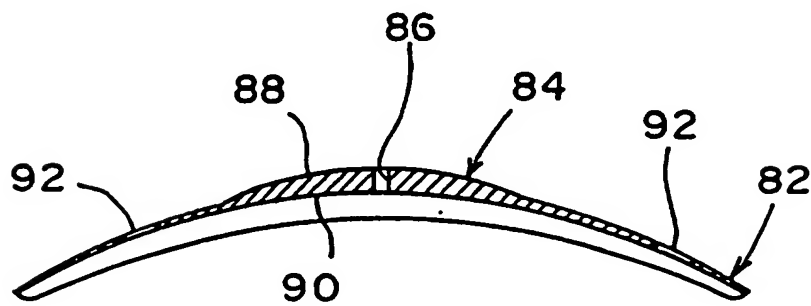


FIG. 23

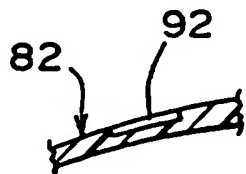


FIG. 24

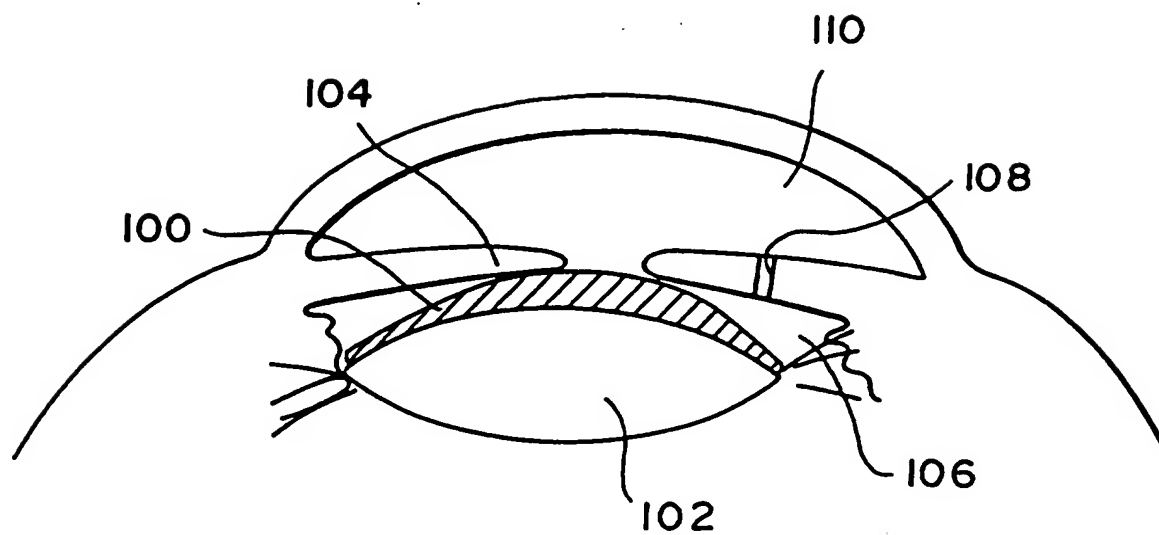


FIG. 25

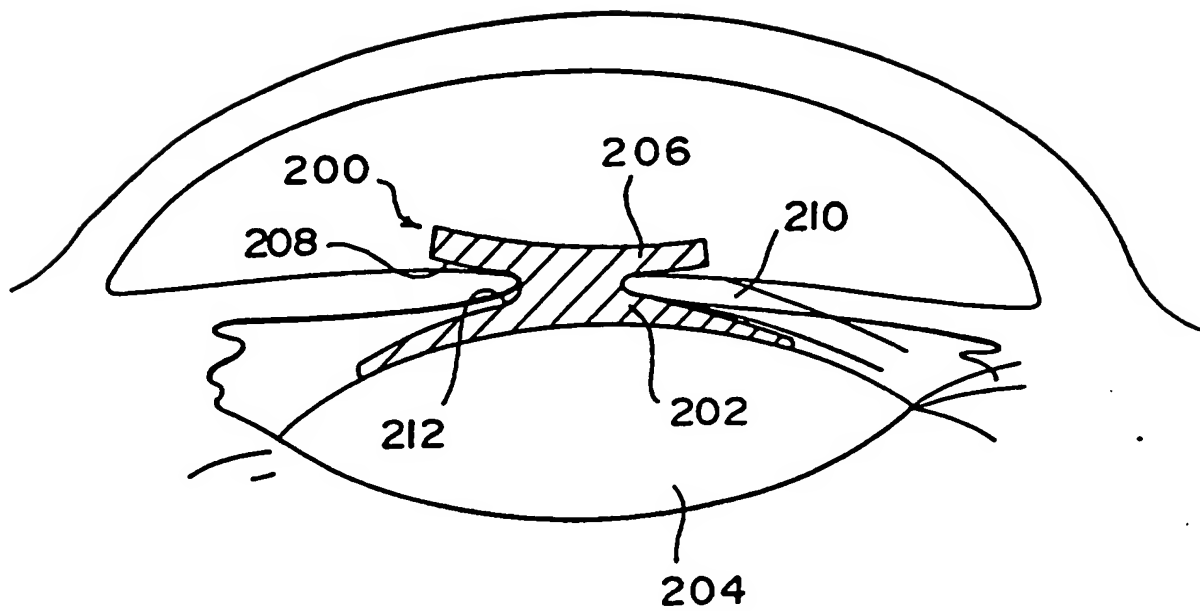


FIG. 26
(PRIOR ART)

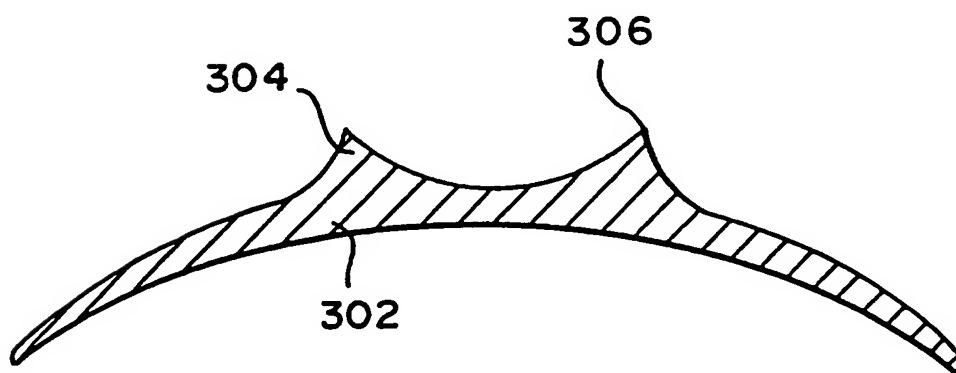


FIG. 27
(PRIOR ART)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/12614**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) : A61F 2/13

US CL : 623/6

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---------------|--|---|
| X --- Y | US, A, 4,449,257 (KOENIGER) 22 MAY 1984, see Fig. 3. | 1, 2, 4-6, 8, 13-15, 17 ----- 7, 16, 18, 19, 22 |
| X --- Y | US, A, 4,816,032 (HETLAND) 28 March 1989, see entire document. | 1, 9, 10, 20, 23, 24 ----- 18, 19, 22 |
| X | US, A, 4,192,022 (LAHAYE) 11 March 1980, see Fig. 1. | 25-27 |

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

| | |
|---|--|
| * Special categories of cited documents: | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" document defining the general state of the art which is not considered to be part of particular relevance | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" earlier document published on or after the international filing date | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "A" document member of the same patent family |
| "O" document referring to an oral disclosure, use, exhibition or other means | |
| "P" document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search

15 NOVEMBER 1995

Date of mailing of the international search report

28 DEC 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Authorized officer

for MARY BETH JONES

Telephone No. (703) 308-3400

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-------------|---|-----------------------|
| X — Y | CONTACTO, JANUARY 1976, (CLAUD A. KENDALL), "Ultrafocal Bifocal Contact Lens" pages 31-35. | 1, 2 |
| Y | US, A, 5,192,318 (SCHNEIDER ET AL.) 09 March 1993, see entire document. | 3 |
| Y | US, A, 4,994,080 (SHEPARD) 19 February 1991, see column 1 lines 28-35. | 18, 19, 22 |

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.